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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/590,038 | 11/17/2006 | Edward Zbygniew Nowak | 086887-0079 | 5625 |

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MCDERMOTT WILL & EMERY LLP
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Washington, DC 20005-3096

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| EXAMINER |
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PURDY, KYLE A

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1611

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| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

06/21/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mweipdocket@mwe.com

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/590,038

Applicant(s)

NOWAK, EDWARD ZBYGNIEW

Examiner

K P

Art Unit

1611

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 31 May 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement(s)*. (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Allison M. Ford/
Primary Examiner, Art Unit 1653

Continuation of 11. does NOT place the application in condition for allowance because:

Applicants arguments filed 5/31/2011 regarding the rejection of claims 16, 18-20, 23, 24, 26, 28, 31, 35 and 40 made by the Examiner under 35 USC 102(b) over Inaba et al. (US 4552751) have been fully considered but they are not persuasive.

In regards to the 102(b) rejection, Applicant asserts the following:

A) Inaba is silent regarding the transport of the drug contained in the film forming organic solvent into the inactive non-gelating polymeric film and is silent regarding the complete absorption of the drug from the solvent into the the non-gelatin polymeric film. Inaba contains multiple films formed on top of one another and not a single film.

In response to A, the mode of transport and absorption into the non-gelatin polymeric film is immaterial. So long as the final structure of the art reads on the product produced by the instant claims (i.e. a multilayered film with active drug layers layered between inactive polymeric layers), rejection/anticipation is appropriate. Inaba discloses a multilayer dosage film wherein drug layers are present within non-gelatin inactive polymeric layers which is identical to the product formed by the instantly claimed process. With respect to Inaba not forming a single film, this argument is not persuasive. The multilayered film of Inaba is a single film in that the multilayers (drug layers and polymeric layers) are annealed together to form a single contiguous film product. This contiguous multilayered film product is a single film while also having multiple polymeric layers. However, it's noted that Applicants claims require multiple layers (up to 40) so this particular argument is not fully understood.

Applicants arguments filed 5/31/2011 regarding the rejection of claims 25 and 32 made by the Examiner under 35 USC 103(a) over Inaba in view of Fagen et al. (US 2003/0183643) have been fully considered but they are not found persuasive.

In regards to the 103(a) rejection, Applicant asserts the following:

B) The anticipatory rejection over Inaba is inadequate therefore the obviousness rejections including Inaba are inadequate.

In response to B, the Examiner respectfully disagrees. For detailed reasons why Inaba is not inadequate as an anticipatory reference, see the Examiners response to assertions A.

Applicants arguments filed 5/31/2011 regarding the rejection of claims 21, 22 and 37-39 made by the Examiner under 35 USC 103(a) over Inaba in view of Patel et al. (US 2004/0253434) have been fully considered but they are not found persuasive.

In regards to the 103(a) rejection, Applicant asserts the following:

C) The anticipatory rejection over Inaba is inadequate therefore the obviousness rejections including Inaba are inadequate.

In response to C, the Examiner respectfully disagrees. For detailed reasons why Inaba is not inadequate as an anticipatory reference, see the Examiners response to assertions A.

Applicants arguments filed 5/31/2011 regarding the rejection of claim 30 made by the Examiner under 35 USC 103(a) over Inaba in view of Brown et al. (US 6783768) have been fully considered but they are not found persuasive.

In regards to the 103(a) rejection, Applicant asserts the following:

D) The anticipatory rejection over Inaba is inadequate therefore the obviousness rejections including Inaba are inadequate.

In response to D, the Examiner respectfully disagrees. For detailed reasons why Inaba is not inadequate as an anticipatory reference, see the Examiners response to assertions A.

Applicants arguments filed 5/31/2011 regarding the rejection of claims 33 and 34 made by the Examiner under 35 USC 103(a) over Inaba in view of Fagen and Lynn et al. (US 7112361) have been fully considered but they are not found persuasive.

In regards to the 103(a) rejection, Applicant asserts the following:

E) The anticipatory rejection over Inaba is inadequate therefore the obviousness rejections including Inaba are inadequate.

In response to E, the Examiner respectfully disagrees. For detailed reasons why Inaba is not inadequate as an anticipatory reference, see the Examiners response to assertions A.